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	GTON BUILDING		COOK, JONATHON	
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			2886	
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			04/11/2008	ELECTRONIC

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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	Application No.	Applicant(s)		
	10/516,810	GELIKONOV ET AL.		
Office Action Summary	Examiner	Art Unit		
	JONATHON D. COOK	2886		
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address		
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period versilier to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin vill apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONE	L. viely filed the mailing date of this communication.		
Status				
Responsive to communication(s) filed on <u>3/28/</u> This action is <b>FINAL</b> . 2b)☑ This     Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro			
Disposition of Claims				
4) ☐ Claim(s) 1-7 and 36-63 is/are pending in the ap  4a) Of the above claim(s) is/are withdray  5) ☐ Claim(s) is/are allowed.  6) ☐ Claim(s) 1-7 and 36-63 is/are rejected.  7) ☐ Claim(s) is/are objected to.  8) ☐ Claim(s) are subject to restriction and/or	vn from consideration.			
Application Papers				
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex	epted or b) objected to by the Eddrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).		
Priority under 35 U.S.C. § 119				
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>				
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3/27/2008.	4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal P 6)  Other:	ite		

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### **Detailed Action**

#### **Continued Examination Under 37 CFR 1.114**

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 3/28/2008 has been entered.

### **Allowable Subject Matter**

The indicated allowability of claims 1-7 is withdrawn in view of the newly discovered reference(s) to 5,321,501 & 6,124,930. Rejections based on the newly cited reference(s) follow.

# Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1-7, 36-41, 43-47, 49-54, & 56-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Swanson et al** (US PAT 5,321,501) (Swanson) in view of **Fercher** (US PAT 6,124,930) (Fercher).

Regarding **Claim 1**, Swanson discloses and shows in **figs. 1 & 4b** a method and apparatus for optical imaging with means for controlling the longitudinal range of the sample, the steps of the method comprising:

directing one part of a low coherence optical source (12) towards a sample (84) (applicant's associated object) within the scanning/sample assembly (28) through an optical system, which ensures focusing the low coherence optical radiation on the sample;

a mechanism (107) for scanning the low coherence optical radiation being directed toward a sample over a transverse scanning surface, that is approximately orthogonal to the direction of propagation of the optical radiation (Column 13, lines 21-30);

directing another part of the low coherence optical radiation along a fiber optic path (30) (applicant's reference optical path) to a reference assembly (32);

combining an optical radiation having returned from the sample (84) within the scanning/sample assembly (28) with the optical radiation returned from the reference assembly (32) (Column 8, lines 13-20);

visualizing an intensity of the optical radiation having returned from the sample using the optical radiation that is a result of the combining (**Column 8, lines 36-44**);

Though implied by the system displayed in **fig. 4b** Swanson does not explicitly disclose providing a constant propagation time for the low coherence optical radiation propagating from a given point of the transverse scanning surface to a corresponding conjugate point of an image plane, thereby eliminating a transverse scanning related aberration of an optical path length for the low coherence optical radiation directed toward an associated object;

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However, Fercher teaches and shows in **fig. 2** a method and arrangement for transverse optical coherence tomography, comprising:

beam bundle (6) focused by a focusing optics (8) in the object-side focal plane (22') (applicant's transverse scanning surface) such that the optical lengths from a focal point (21) (applicant's corresponding conjugate point of an image plane) to the object-side focal plane (22') are equal (applicant's providing a constant propagation time for the low coherence optical radiation) (Column 3, lines 20-27);

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Swanson with providing a constant propagation time for the low coherence optical radiation propagating from a given point of the transverse scanning surface to a corresponding conjugate point of an image plane because it would remove the change in optical path length in the measurement beam and also any additional frequency modulation of the interferometer signal which reduces imaging errors and distorted image surfaces (Column 3, lines 27-30 & Column 2, lines 44-47), as taught by Fercher.

Regarding Claims 2 & 4, Swanson discloses and shows in fig. 4b performing longitudinal scanning of the sample by longitudinally moving (applicant's altering the optical path length for the low coherence optical radiation propagating from the sample to the optical system) a lens (109) (Applicant's varying a difference between optical path lengths between the reference and sample paths to perform longitudinal scanning for a given coordinate in the sample in compliance with a predetermined rule) (Column 13, lines 30-35).

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Regarding **Claim 3**, Swanson discloses the aforementioned but does not explicitly disclose the difference varied between the optical paths is at least several tens of wavelengths of the low coherence optical radiation;

However, this is merely an optimization to insure the entire width of the coherence length is scanned;

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the difference between the optical paths by at least several tens of wavelengths of the low coherence optical radiation, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding **Claim 5**, Swanson discloses the apparatus is for performing measurements on biological (applicant's biological tissue) and other samples (**Column 1, lines 13-15**);

Regarding **Claim 6**, Swanson discloses the sample, for example adjacent to a patient's eye for scanning and imaging or taking measurements on the patient's eye, or it may be adapted to be positioned inside the sample, being, for example, part of an angioscope or endoscope for scanning internal body or other channels (Applicant's internal cavity of a living body) (**Column 6**, **lines 17-22**).

Regarding Claim 7, Swanson discloses that the light from the diode (12) may be in the infrared region (Column 5, lines 63-64).

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Regarding Claims 36 & 49, Swanson discloses and shows in figs. 1 & 4b a method and apparatus for optical imaging with means for controlling the longitudinal range of the sample, the apparatus comprising:

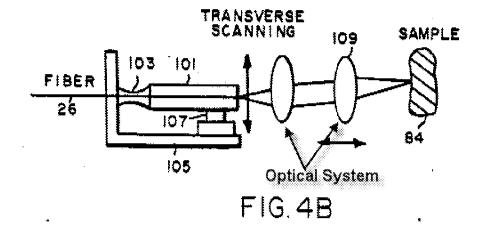
a short coherence length optical source (12) (applicant's source of low coherence optical radiation);

an optical coherence domain reflectometer (OCDR) (10) (applicant's interferometer) coupled to the source (12), the interferometer including a coupler (22) (applicant's beam splitter) coupled with a first fiber optic path (26) (applicant's measuring arm) and a second fiber optic path (30) (applicant's reference arm);

a photodetector (52) connected with a computer (72) (applicant's data processing unit) and display (76) (applicant's display unit);

the measuring arm being provided with a delivering device comprising:

an optical fiber (26) optically coupled with an optical system (See modified figure 4b) and a transverse scanning/sample assembly (28) (applicant's transverse scanning system);



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#### (modified figure 4b)

The optical fiber is positioned to allow for the low coherence optical radiation to pass from the proximal end of the delivering device to it's distal end, where the optical fiber is incorporated into the transverse scanning system (Column 13, lines 19-20), which is configured to move the end face of the distal part of the optical fiber over the transverse scanning surface in a direction approximately perpendicular to an axis of the optical fiber (Column 13, lines 29-38);

The optical system provides focusing of the low coherence optical radiation onto the sample, the optical system being of a first and second lens with positive focal power (see fig 4b);

Though implied by the system displayed in **fig. 4b** Swanson does not explicitly disclose the first and second lens positioned to provide a constant propagation time for the low coherence optical radiation propagating from a given point of the transverse scanning surface to a corresponding conjugate point of an image plane, thereby eliminating a transverse scanning related aberration of an optical path length for the low coherence optical radiation directed toward an associated object;

However, Fercher teaches and shows in **fig. 2** a method and arrangement for transverse optical coherence tomography, comprising:

beam bundle (6) focused by a focusing optics (8) in the object-side focal plane (22') (applicant's transverse scanning surface) such that the optical lengths from a focal point (21) (applicant's corresponding conjugate point of an image plane) to the object-

side focal plane (22') are equal (applicant's providing a constant propagation time for the low coherence optical radiation) (Column 3, lines 20-27);

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Swanson with the first and second lens positioned to provide a constant propagation time for the low coherence optical radiation propagating from a given point of the transverse scanning surface to a corresponding conjugate point of an image plane because it would remove the change in optical path length in the measurement beam and also any additional frequency modulation of the interferometer signal which reduces imaging errors and distorted image surfaces (Column 3, lines 27-30 & Column 2, lines 44-47), as taught by Fercher.

With regard to **claim 36**, language that does not limit a claim limitation to a particular structure does not limit the scope of the claim. It has been held that the recitation that an element is "adapted to", "configured to", "designed to", "for", or "operable to" perform a function is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 139. Such is true for all the claims 36-63.

Regarding Claims 37 & 50, Swanson discloses and shows in fig. 4a a sample (84') is the human eye (applicant's transverse scanning surface having a non-zero curvature).

Regarding Claims 38 & 51, Swanson discloses and shows in fig. 4b the optical fiber (26) serves as a flexible cantilever and is attached to a stationary housing (105)

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through a pivot joint (103) (applicant's bearing support) incorporated into the delivering device for low coherence optical radiation.

Regarding Claims 39 & 52, Swanson shows in fig. 4b the first and second lens of the optical system are positioned substantially confocally.

Regarding Claims 40, 41, 53, & 54, Swanson discloses and shows in fig. 4b the aforementioned but does not explicitly disclose the positioning of the lenses according to the claimed limitations;

However this is merely an optimization of lens positioning and the equations for such are well known in the art;

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the lenses accordingly, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding Claims 43, 44 & 60, Swanson discloses and shows in fig. 4b performing longitudinal scanning of the sample by longitudinally moving (applicant's altering the optical path length for the low coherence optical radiation propagating from the sample to the optical system) a lens (109) (Applicant's varying a difference between optical path lengths between the reference and sample paths to perform longitudinal scanning for a given coordinate in the sample in compliance with a predetermined rule) (Column 13, lines 30-35).

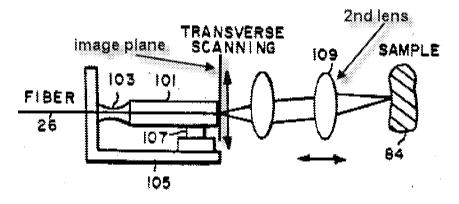
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Regarding Claims 45, 46, 61, & 62, Swanson discloses and shows the aforementioned. While Swanson does not explicitly address the magnification factor of the optical system which is dependent on the refractive indices N1 or N2 examiner finds the claimed limitations are met since the magnification is an inherent property of the object being scanned or the medium between it and the apparatus as disclosed.

Regarding **Claim 47**, Swanson disclose and shows the aforementioned further it can be seen from **fig. 4b** that the device for longitudinal scanning is within the delivering device for low coherence optical radiation.

Regarding Claims 56 & 57, Swanson as modified by Fercher teaches and shows the aforementioned and further shows in fig. 4b an output window of the delivering device for low coherence optical radiation is arranged near the image plane of the end face of the distal part of the optical fiber and the second lens component of the optical system serves as the output window of the delivering device (see second modified figure 4b);



(second modified figure 4b)

Regarding **Claim 58**, Swanson discloses and shows the aforementioned but fails to disclose a normal line to an outer surface of an output window of the delivering

device is orientated at an angle to the direction of incidence of the low coherence optical radiation on the outer surface, the angle exceeding a divergence angle of the low coherence optical radiation at a place of its intersection with the outer surface;

However, Fercher teaches and shows in **fig. 4** that transverse tomographs can be acquired at any desired angles, the figure shows the claimed limitation of lens orientation to direction of incidence of the optical radiation;

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Swanson with a normal line to an outer surface of an output window of the delivering device is orientated at an angle to the direction of incidence of the low coherence optical radiation on the outer surface, the angle exceeding a divergence angle of the low coherence optical radiation at a place of its intersection with the outer surface for advantages such as reducing noise from backscattered light.

Regarding **Claim 59**, Swanson discloses and shows in **fig. 4b** the aforementioned but does not explicitly disclose the positioning of the second lens with the claimed offset;

However this is merely an optimization of lens positioning;

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the lenses accordingly, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

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3. Claims 48 & 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Swanson** in view of **Fercher** and further in view of **Swanson et al** (US PAT 6,445,939) (Swanson939).

Regarding **Claims 48 & 63**, Swanson as modified by Fercher teaches the aforementioned but fails to disclose a microlens rigidly attached to the optical fiber.

However, Swanson939 teaches and shows in **figs. 2A-E** optical fiber-lens systems having different types of microlenses (2) that are rigidly attached to the fiber;

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Swanson as modified by Fercher with the microlens rigidly attached to the fiber as in the teachings of Swanson because medical diagnostic techniques which rely on measuring the optical properties of a narrow, twisting lumen (e.g., small arteries and veins) or a small space (e.g., pulmonary airways) require ultra-small optical probes. These probes in turn require ultra-small imaging lenses (Column 1, lines 14-18), as taught in Swanson939.

4. Claims 42 & 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Swanson** in view of **Fercher** and further in view of **Applicant's Admitted Prior Art** (AAPA);

Regarding Claims **42 & 55**, Swanson discloses and shows the aforementioned and further discloses and shows in **fig. 5** angioscope or endoscope (applicant's fiber probe) with inner and outer sheaths (**122 & 124**) which distal end of the fiber (26) is

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embedded in the inner sheath (122) (applicant's throughhole with the fiber extending through it);

Swanson fails to disclose the optical system of **fig. 4b** being encased within the elongated body of the optical probe;

However, the AAPA discloses known measuring probes are designed typically as an optical fiber probe comprising an optical fiber positioned in such a way, that low coherence optical radiation can pass from its proximal end to its distal end, and an optical system which focuses the low coherence optical radiation on the object. The optical system includes at least one lens component with positive focal power. The measuring probe includes also a system for transverse scanning of the low coherence optical radiation. The measuring probe typically has an elongated body with a throughhole extending therethrough, wherein an optical fiber extends (*Page 2, lines 2-8*);

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the optical system disclose integral to the fiber probe, since it has been held that integrating previously known parts without producing any new and unexpected result involves only routine skill in the art. In re Larson 340 f.2d 965 144 USPQ 347 (CCPA 1965).

## Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHON D. COOK whose telephone number is (571)270-1323. The examiner can normally be reached on Mon-Fri 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tarifur Chowdhury can be reached on (571)272-2287. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jonathon Cook Patent Examiner AU:2886 April 4<sup>th</sup>, 2008

/TARIFUR R CHOWDHURY/
Supervisory Patent Examiner, Art Unit 2886